

Remarks

Claims 22-25, 34-37, 46 and 47 are pending in this application. Claims 22 and 36 have been amended without prejudice or disclaimer. No new matter has been added with these amendments. Applicants reserve the right to prosecute any cancelled or otherwise unclaimed subject matter in this or a separate application, as appropriate. Consideration and entry of these remarks and amendments is respectfully requested.

**A. Rejections Under 35 U.S.C. § 103(a) over Hildebrand in view of Whitehead**

Claims 22, 23, 25, 34-37, 46 and 47 stand rejected under 35 U.S.C. 103(a) as unpatentable over Hildebrand (US 2003/0166057) in view of Whitehead (U.S. Pat. No. 4,554,088). Applicants respectfully disagree and traverse these rejections as discussed below.

The Examiner alleged that Hildebrand teaches recombinant class II HLA molecules and that the same “can be used in methods for the removal of anti-HLA antibodies.” The Examiner admitted that Hildebrand fails “to teach the step of contacting the sample and removing the bound anti-HLA antibodies.” The Examiner alleged that Whitehead discloses “methods for depleting a sample of a biological molecule of interest by contacting the sample with an immobilized bioaffinity absorbent.” The Examiner concluded that the subject matter of the instant claims would have been obvious because of what Hildebrand and Whitehead teach. The Examiner provides no reasoning as to why one of skill in the art would have been motivated to make this combination, and is required to do so in a proper *prima facie* showing of obviousness.

While an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim”, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007) (citing In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006)). As stated at MPEP 706.02(j) (July, 2008):

It is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply.

In this rejection, the Examiner did not provide any explanation relating to a motivation to combine the cited references. Instead, the Examiner provided mere conclusions that because Hildebrand alleged their recombinant class II molecules could be used for “removal of anti-HLA antibodies from a patient” and Whitehead allegedly teaches “removing a biological molecule from a sample”, the claimed subject matter would have been obvious. The Examiner did not support the conclusions as required by the U.S. Supreme Court, the Federal Circuit, and the USPTO (MPEP 706.02(j)). Thus, Applicants believe that the Examiner did not establish a *prima facie* case of obviousness of the pending claims and therefore respectfully request withdrawal of the rejections.

**B. Rejections Under 35 U.S.C. § 103(a) over Whitehead in view of Viken**

Claims 22, 23, 25, 34-37, 46 and 47 stand rejected under 35 U.S.C. 103(a) as unpatentable Whitehead (U.S. Pat. No. 4,554,088) in view of Viken et al. (Human Immunology, Vol. 44, 1995, pp. 63-69). Applicants respectfully disagree and traverse these rejections as discussed below.

The Examiner alleged that Whitehead discloses a bioaffinity adsorbent that may be used to deplete a sample of a biological molecule. The Examiner admitted that Whitehead does not teach a recombinant MHC Class II or HLA Class II molecule or an antibody thereto. This, the Examiner alleged, is taught by Vilken (“...the bioaffinity adsorbents can be recombinant HLA Class II molecules which bind specifically to antibodies of a sample (anti-HLA antibodies).”) Thus, the Examiner concluded that the claimed subject matter would have been obvious:

... because Whitehead is generic with respect to the biological molecule to be depleted and one would use the appropriate bioaffinity reagent, i.e. recombinant HLA molecule to deplete the desired biomolecule of interest, in this case MHC molecule antibodies. Thus, one of ordinary skill in the art would have a reasonable expectation of success incorporating recombinant molecules such as taught by Viken et al. into the method of Whitehead et al.

In making this conclusion, the Examiner provided no reasoning as to why one of skill in the art would have been motivated to make this combination, and is required to do so in a proper *prima facie* showing of obviousness.

While an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim”, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007) (citing In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006)). As stated at MPEP 706.02(j) (July, 2008):

It is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply.

In this rejection, the Examiner did not provide any explanation relating to a motivation to combine the cited references. Instead, the Examiner merely concluded that one could have done so and therefore the claimed subject matter would have been obvious. The Examiner did not support the conclusions as required by the U.S. Supreme Court, the Federal Circuit, and the USPTO (MPEP 706.02(j)). Thus, Applicants believe that the Examiner has not established a *prima facie* case of obviousness of the pending claims and therefore respectfully request withdrawal of the rejections.

#### **C. Rejections Under 35 U.S.C. § 103(a) over Hildebrand in view of Whitehead and Lee**

Claims 22, 23, 25, 34-37, 46 and 47 stand rejected under 35 U.S.C. 103(a) as unpatentable over Hildebrand (US 2003/0166057) in view of Whitehead (U.S. Pat. No. 4,554,088) as discussed above, and further in view of Lee et al. (U.S. Pat. No. 6,150,122). Applicants respectfully disagree and traverse these rejections as discussed below.

In the rejection discussed in part A above, the Examiner alleged that Hildebrand teaches recombinant class II HLA molecules and that the same “can be used in methods for the removal of anti-HLA antibodies.” The Examiner admitted that Hildebrand fails “to teach the step of contacting the sample and removing the bound anti-HLA antibodies.” The Examiner also alleged that Whitehead discloses “methods for depleting a sample of a biological molecule of interest by contacting the sample with an immobilized bioaffinity absorbent.” And the Examiner concluded that the subject matter of claims 22, 23, 25-37, 46 and 47 would have been obvious in view of those references.

In this rejection, the Examiner also alleged that Lee taught that it was known in the art that “serum samples from patients comprise [anti]-HLA antibodies” and “immobilized class II antigens for binding to the antibodies of the sample.” Thus, the Examiner concluded that the claimed subject matter would have been obvious:

. . . because Hildebrand et al and Whitehead et al are generic with respect to the sample and because Lee et al shows that it is known in the art that serum samples comprise anti-HLA antibodies and one would use the appropriate sample to remove the desired antibodies, in this case anti-HLA antibodies. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating a serum sample such as taught by Lee et al. into the modified method of Hildebrand et al.

In making this conclusion, the Examiner provided no reasoning as to why one of skill in the art would have been motivated to make this combination, and is required to do so in a proper *prima facie* showing of obviousness.

While an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim”, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007) (citing In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006)). As stated at MPEP 706.02(j) (July, 2008):

It is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply.

In this rejection, the Examiner did not provide any explanation relating to a motivation to combine the cited references. Instead, the Examiner merely concluded that one could have done so and therefore the claimed subject matter would have been obvious. The Examiner did not support the conclusions as required by the MPEP, and addressed by both the Federal Circuit Court of Appeals and the U.S. Supreme Court. Thus, Applicants believe that the Examiner has not established a *prima facie* case of obviousness of the pending claims and therefore respectfully request withdrawal of these rejections.

**Conclusions**

Applicants believe that a full and complete Reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned. Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully Submitted,

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